

constitute a reward for manufacturers, however, various benefits have been reported such as reimbursement for drugs which received an initial negative recommendation (e.g. bortezomib and trabectedin, UK) and competitive advantage in the form of better formulary position (sitagliptin & sitagliptin + metformin, USA); not to mention the possibility of granting discounts while leaving list prices untouched. Considerable administrative burden is placed on health care staff due to the diversity of existing schemes, the complexities linked with retrospective reimbursement, and lack of management capacity at current staffing levels. **CONCLUSIONS:** Although evidence on the impact of MEs is patchy, the systematic literature review showed that there are already lessons to be learnt. Preliminary findings seem to suggest that MEs have indeed the potential of meeting payer, patient, and manufacturer expectations, yet important threats such as implementation difficulties, administrative burden and lack of management capacity need to be addressed.

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THE ADMINISTRATIVE BURDEN OF PATIENT ACCESS SCHEMES IN THE CHANGING UK HEALTH CARE SYSTEM: A FOLLOW UP STUDY

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OBJECTIVES: In the UK, Patient Access Schemes (PAS) have become common in health technology submissions, and have been instrumental in enhancing the availability of otherwise non cost-effective treatments. Despite notable efforts towards recognising and reducing the administrative impact of PAS on frontline staff, evidence suggests that they still result in a significant burden. The study presented here attempted to assess the burden of PAS administration, and how this could change if and when the planned changes to the UK healthcare system are enacted. **METHODS:** A literature search was conducted and freedom-of-information requests were sent to the Patient Access Scheme Liaison Unit (PASLU) for data on PAS administration. A questionnaire developed from our previous pilot study on the administrative burden of PAS was distributed to hospital pharmacists across the UK, and a call for participants was hosted on the Royal Pharmaceutical Society website. **RESULTS:** Value Based Pricing (VBP) is expected to be introduced in the UK once the current Pharmaceutical Price Regulation Scheme comes to an end. PAS approved before this point will continue to be used, although additional PAS may not be introduced under VBP. It is unclear from the available literature how this will affect the role of PASLU and the administration of the remaining PAS. The return-rate for our questionnaire was low; however, responders voiced similar concerns to those recorded in our pilot study, namely the poor recognition of the burden of PAS and the resources required to manage them. Responders were also unclear about how administration of PAS would change with the move to VBP. **CONCLUSIONS:** The role of PAS in the changing NHS, and the burden such schemes could entail, is uncertain. Clear guidelines on the impact of healthcare reform are necessary, alongside additional support to facilitate effective PAS implementation even after VBP is introduced.

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SOME SHORTAGES AND ALTERNATIVES TO THE PATENT SYSTEM FOR PHARMACEUTICALS

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OBJECTIVES: Pharmaceutical patents have been a useful instrument to promote innovations in some fields. The signature of the TRIP agreement by the World Trade Organization (WTO) in 1994 has implied the generalization of a strong patent system. The objectives of this study is to review some existing alternatives to patents that may both reduce their negative impact in the accessibility to new drugs of patients from less developed countries and promote research in neglected diseases. **METHODS:** We have reviewed the literature on this field and identified different alternatives proposed by international institutions as well as by non governmental organisations. We describe the options and assess their potential impact on public health. **RESULTS:** There are several proposals: i) the intensive use of exceptions and flexibility conditions of Doha's Declaration, especially, compulsory licensing, ii) the volunteer licensing through the "patent pool", iii) GSPOA initiative that targets the identification and assessment of priorities dealing with R&D referred to diseases prevalent among the developing countries, iv) the approach based on prizes, aiming to incentive innovation through competition by separating the cost of R&D and the price of the drug; v) the Advance Market Commitments to ex-ante obtain the commitment to fund through donations the new agent once it has been developed, and vi) the Priority Review Vouchers that provides incentives to invest in drugs for neglected tropical diseases by offering a transferable voucher to the pharmaceutical firm that allows a priority review process for the authorisation of another agent. **CONCLUSIONS:** Most of the solutions are partial and do not pursue a radical change in the current patent system. In spite of these proposals, there are still many diseases with no treatment as the market does not guarantee a return.

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IRANIAN HEALTH SYSTEM DECENTRALIZATION REFORM: A QUALITATIVE STUDY OF VARIOUS LEVELS OF AUTONOMY GRANTED TO PUBLIC HOSPITALS AFFILIATED WITH MINISTRY OF HEALTH IN IRAN

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OBJECTIVES: We aimed to explore the key organizational elements and the degrees of autonomy that is granted to Iranian corporatized hospital (trustees hospitals) affiliated to Iranian ministry of health after the Iranian health system decentralization reform. **METHODS:** All 18 Iranian corporatized hospitals (that meet our criteria) involved to the study. In all, 27 Hospital Top Managers were interviewed (82% response rate). The semi-structured interview questions were developed using the Preker and Harding organizational reform Model and in-depth interviews. The "framework" method was used for the analysis. **RESULTS:** Nine themes explain the key organizational elements include: decision right in "strategic", "human resources", "financial" and "physical resources" management, "product" and "procurement" market exposure, "residual claimant" and "social functions". Decision right in "strategic", "human resources" and "physical resources" management was very limited. The hospitals were permitted to generate revenue (fee-for-services) but weren't the residual claimant, completely. The hospital was exposed to product market but limited in procurement market (ceiling payment). Hierarchical and financial accountability were the main accountability mechanism. Several insurance programs and governmental budget were used to protect poor people. **CONCLUSIONS:** We can see a kind of unbalanced and inconsistent autonomy. More decision right in "strategic" and "human resources" management, and procurement market should be granted; and also the hospital needs to be the residual claimant. Government needs a regulatory and accountability mechanism to guarantee hospitals performance and balance the revenue generating and social values objectives.

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REVIEW OF COST EFFECTIVENESS MODELS OF HIGH BUDGET IMPACT DRUGS

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OBJECTIVES: The recently made coverage decisions by UK's NICE, Scotland's SMC and the allocation of \$1.1 billion for comparative effectiveness research by the United States, are strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top twenty highest selling drugs (~\$90-100B worldwide sales). **METHODS:** The Top 20 drugs were selected based on their worldwide sales. For this analysis, we segmented these drugs into categories as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. We analyzed the cost effectiveness studies that were published in peer-reviewed journals. Search was conducted using generic names of the drugs and the phrase "cost effectiveness" in abstract of the published study. **RESULTS:** During 2005-2010, the number of published studies on "cost effectiveness" have increased by more than 30%. There is a large variability in CERs for same drugs for different indications, in some cases also varying by biomarkers. Primary care drugs had lower and less variable CERs than specialty drugs. Variations also exist in methodology used by different groups in modeling cost effectiveness, especially for time horizon and comparator. Majority of primary care drugs were modeled for a time horizon of 35-40 years or lifetime to demonstrate cost effectiveness. **CONCLUSIONS:** This analysis shows the range, variability and methods used for calculation of ICER values for these high budget impact drugs and provides lessons for executives and policy makers.

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NOVEL DRUG REIMBURSEMENT MODELS: LESSONS AND IMPLICATIONS FROM CANCER DRUG ACCESS SCHEMES

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OBJECTIVES: Cancer drugs are the world's highest selling category of therapeutic products. Due to their premium price and budget impact, several new drug reimbursement models have been implemented worldwide by public and private payers. These models have potential implications for coverage and reimbursement of all branded products. This study reviewed recent cancer drug reimbursement models and developed lessons and implications for future products. **METHODS:** Reviewed cancer drug reimbursement schemes in developed and emerging markets. Interviewed payers and KOLs to develop lessons and implications for future products. **RESULTS:** Public and private payers worldwide have implemented several new models for cancer drug reimbursement to manage budgets and control costs. In the US, private payers are piloting single source compendia and third party protocols (eg. P4 Oncology) to limit off-label use of cancer drugs. In the UK, NICE has successfully negotiated lower price and discounts for first few cycles of therapy. In Italy, AIFA has implemented registry based patient access for cancer drugs. In India, several manufacturers have implemented novel pricing strategy for first few cycles of therapy. In Germany, IQWiG has proposed to use correlations between surrogate endpoints and patient relevant outcomes to determine value of cancer drugs. Due to increased cost pressure on payers, such models are likely to inspire novel reimbursement schemes for other branded products. **CONCLUSIONS:** Cancer drug reimbursement models are setting new benchmark for payers to manage access and control costs. These models have significant implications for other expensive branded products.

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USING THE CEAC FOR VALUE BASED PRICING: DON'T CHANGE THE GOALPOSTS

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ISSUE One approach under consideration for the proposed value based pricing of pharmaceutical is the UK is to have different willingness to pay thresholds. However these are problematic to define, lack transparency and not readily understood by the wider public. **OVERVIEW** Different willingness to pay thresholds have been